K130886

APR 2 5 2013

SECTION 7

510(k) Summary (21 CFR § 807.92(c))

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter:	Glooko, Inc. 170A University Avenue Palo Alto, CA 94301
Contact:	Shilpa Mydur Regulatory Affairs Manager Phone: 650.720.5310 Email: shilpa@glooko.com
Date Summary Prepared:	22 April 2013
Device Trade Name:	Glooko Device System for Glooko Logbook+ Application
Common Name:	Blood Glucose Meter and Data Management System
Classification Name:	Glucose test system (21 CFR §862.1345) Calculator/data processing module for clinical use (21 CFR §862.2100)
Product Code:	NBW and JQP
Equivalent Device:	Glooko Device System for Glooko Logbook Application and Glooko Logbook Charts (K122142)

Device Description:

Overview

The Glooko device system for Glooko Logbook+ Application is used to aid individuals with diabetes in the download, review, analysis, evaluation, and communication of their blood glucose readings. The system allows users to download readings from compatible, FDA-cleared, commercial blood glucose meters to their iPhone Operating System (iOS) devices, and then share this information with healthcare professionals. It is intended for use both in home and professional settings to support an effective diabetes management program. The data may be displayed on supported devices to provide an online view of all collected data and notes from the Glooko Logbook+ Application. The system does not provide treatment decisions and cannot be used as a substitute for professional healthcare advice.

The Glooko device system for Logbook+ Application consists of the following components

1. The **Glooko MeterSync Cable**
2. The **Glooko IR Adapter**
3. The **Glooko Logbook+ Application**

Glooko MeterSync Cable

The Glooko MeterSync Cable downloads data from compatible, FDA-cleared, commercial blood glucose meters into an iOS device by connecting the two components. One end of the Glooko MeterSync Cable plugs directly into the 30-pin connector slot of the iOS device. The 3.5mm end of the Glooko MeterSync Cable plugs directly into most compatible meters to allow for the transfer of data. Some meters require an additional 3.5mm to 2.5mm adapter to allow for this connectivity, while other meters transfer data through infrared, and thus require the use of the Glooko IR Adapter.

The Glooko MeterSync Cable is designed to attach to a variety of compatible, FDA-cleared, commercial blood glucose meters. The users simply connect the supported meters to their iOS device and transfer the blood glucose meter data into the Glooko Logbook+ Application.

Glooko IR Adapter

The Glooko IR Adapter is designed to transmit data via infrared from a variety of compatible, FDA-cleared, commercial blood glucose meters into the Glooko Logbook+ Application. The user connects the Glooko IR Adapter to the 3.5mm adapter end of the Glooko MeterSync Cable to transmit data from the compatible meters.

The Glooko Logbook+ Application:

The Glooko Logbook+ Application is one component of the Glooko data monitoring system used to aid individuals with diabetes in the review, analysis, evaluation, and communication of their blood glucose readings.

The Glooko Logbook+ Application collects and stores historical blood glucose data that has been downloaded from blood glucose meters. The Glooko Logbook+ Application also lets the user sync and view data from any supported compatible device when using the appropriate login information.

The Glooko Logbook+ Application keeps an organized log of the users blood glucose readings and allows for the addition of user-generated notes and meal tags. The Glooko Logbook+ Application also shows graphs, provides statistics, and allows for the sharing and viewing of blood glucose data across multiple supported devices. The user can also create goals as they aim to manage their blood glucose readings.

The Glooko Logbook+ Application is compatible with the following FDA-cleared blood glucose meters:

- **Abbott:** FreeStyle Freedom Lite®, FreeStyle Lite®
- **ARKRAY:** GLUCOCARD® 01, GLUCOCARD® Vital™
- **Bayer:** Bayer's BREEZE®2, Bayer's CONTOUR®, Bayer's CONTOUR® NEXT EZ.
- **iSens:** CareSens N and CareSens N POP
- **LifeScan:** OneTouch® Ultra®2, OneTouch® UltraLink®, OneTouch® UltraMini®
- **ReliOn:** ReliOn® Confirm, ReliOn® Prime
- **Roche:** ACCU-CHEK® Aviva, ACCU-CHEK® Compact Plus, ACCU-CHEK® Nano

The Glooko Logbook+ Application can be operated on the following iOS devices, each supporting iOS 5.0 and higher:

- **iPod touch®:** 3rd and 4th generations
- **iPhone®:** 3GS, 4, 4S, 5
- **iPad®:** 1st, 2nd, 3rd and 4th generations, iPad mini, – the Glooko Logbook+ Application is not native to the iPad but it can be accessed in 2x mode

The Glooko Logbook+ Application is compatible with the following web browsers:

- **Internet Explorer**- v8.0 and above
- **Firefox**- v3.0 and above
- **Chrome**- v14.0 and above
- **Safari**-v4.0 and above
- **iOS (Safari)**- v3.0 and above

Software Requirements:

The Glooko Logbook+ Application performs the following functions:

- **Sync** with compatible meters
- Allow users to **annotate** readings with notes
- Provide multiple **view** options for the data
- **Graph** the glucose readings
- Provide **statistics**
- Allow for **goals** to be set
- **Share** the collected data
- **Transmit** and **view** readings, graphs, statistics and notes across supported multiple devices and web browsers when using consistent authentication credentials (username and password)

Technological Characteristics:

The table below provides the comparison of technological characteristics between the subject and predicate device

Table 1: Summary of Technological Characteristics

Product	Glooko device system for Logbook Application and Glooko Logbook Charts (K122142)	Glooko Device System for Glooko Logbook+ Application (K130886)
Software	Glooko Logbook Application	Glooko Logbook+ Application
Hardware	MeterSync Cable IR Adapter	Same
Blood glucose meter compatibility	Abbott: FreeStyle Freedom Lite®, FreeStyle Lite® Bayer: Bayer's BREEZE®2, Bayer's CONTOUR®, Bayer's CONTOUR® NEXT EZ, Bayer's CONTOUR® XT GLUCOCARD: GLUCOCARD® 01, GLUCOCARD® VitalTM LifeScan: OneTouch® Ultra®2, OneTouch® UltraLink®, OneTouch® UltraMini® ReliOn: ReliOn® Confirm, ReliOn® Prime Roche: ACCU-CHEK® Aviva, ACCU-CHEK® Aviva Nano, ACCU-CHEK® Compact Plus, ACCU-CHEK® Nano	Abbott: FreeStyle Freedom Lite®, FreeStyle Lite® Bayer: Bayer's BREEZE®2, Bayer's CONTOUR®, Bayer's CONTOUR® NEXT EZ, Bayer's CONTOUR® XT GLUCOCARD: GLUCOCARD® 01, GLUCOCARD® VitalTM LifeScan: OneTouch® Ultra®2, OneTouch® UltraLink®, OneTouch® UltraMini® ReliOn: ReliOn® Confirm, ReliOn® Prime Roche: ACCU-CHEK® Aviva, ACCU-CHEK® Aviva Nano, ACCU-CHEK® Compact Plus, ACCU-CHEK® Nano CareSens N and CareSens N POP
Operating System	iOS 4.3 and higher	iOS 5.0 and higher
Hardware	• iPod touch®: 3rd and 4th generations • iPhone®: 3GS, 4, 4S • iPad®: iPad 1, iPad 2, and iPad (3rd generation) – (Accessed in 2x mode)	• iPod touch®: 3rd and 4th generations • iPhone®: 3GS, 4, 4S • iPad®: iPad 1, iPad 2, and iPad (3rd generation) –(Accessed in 2x mode) • iPod touch 5th generation, iPhone 5, iPad mini, and iPad 4th generation (These devices require Apple's off-the-shelf Lightning to 30-pin adapter for connection.)
Syncs with compatible meters	Yes	Yes
Allow users to annotate readings with notes	Yes	Yes

Product	Glooko device system for Logbook Application and Glooko Logbook Charts (K122142)	Glooko Device System for Glooko Logbook+ Application (K130886)
Provide multiple view options for the data	Yes	Yes. Additionally, same data is presented in different ways like List View, Day View, Month View And Logbook View. Readings in List and Logbook views are color-coded to indicate if they are high, low or within range. These features were added for user convenience. These additional features did not raise any new questions about safety and effectiveness.
Share the collected data	Yes	Yes
Provide statistics	Yes via supported web download of Glooko Logbook Charts from PC	Yes, across multiple devices and supported web browsers.
Graph the glucose readings	Yes via supported web download of Glooko Logbook Charts from PC	Yes, across multiple devices and supported web browsers.
Allow goals to be set	No	Yes Goals can be set to help motivate healthy lifestyle choices. The five goals that can be added are limited to: ➢ Test blood glucose regularly ➢ Sync meter more often ➢ Keep readings within range ➢ Add meal tags to readings ➢ Exercise more often. This feature neither affects the blood glucose data nor raises any new questions of safety and effectiveness.

Product	Glooko device system for Logbook Application and Glooko Logbook Charts (K122142)	Glooko Device System for Glooko Logbook+ Application (K130886)
Transmit and view data across supported multiple devices and web browsers using consistent authentication credentials (username/password)	No	Yes, to ensure data security, a login credential feature was added. To protect sensitive health information from unauthorized access during transmission, all data on the Glooko network is protected using the Secure Sockets Layer (SSL) protocol. In addition, Glooko forces the https:// standard for all mobile and web communication features, protecting from unauthorized access over wireless and wired networks. All data in the Glooko system is encrypted end-to-end using 256-bit Advance Encryption Standard (AES) encryption for message data both in transmission and storage.

Intended Use:

The Glooko device system for Glooko Logbook+ application is data management software intended for use in home and professional settings to aid individuals with diabetes and their healthcare professionals in review, analysis and evaluation of blood glucose readings to support an effective diabetes management program. The Glooko device system for Glooko Logbook+ application connects to compatible FDA cleared meters and allows users to transfer their blood glucose meter results to their iPhone operating system platform.

The Glooko device system for Glooko Logbook+ application is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

Summary of Testing:

The Glooko Logbook+ Application underwent verification and validation testing. A brief summary of the tests performed is described below. These studies demonstrated that the Glooko Device System for Glooko Logbook+ Application performed according to the specifications and the intended use.

Software Verification and Validation

- The Glooko Device system (Glooko Logbook+ Application, Cable and Adapter) was validated pursuant to the moderate level of concern requirements. Design

validation testing confirmed that the Glooko device performs according to the stated intended use. Device evaluation consisted of functional testing performed pursuant to Glooko's design verification protocol, which referenced FDA's guidance document for medical devices containing software. Such testing included Data Integrity Verification, Software Design/features Verification, and error handling testing. All test results fell within the pre-determined specification parameters.

Statement of Equivalence:

The Glooko Device System for Glooko Logbook+ Application is substantially equivalent to the predicate device with regards to its intended use and function. Both the subject and predicate devices use the exact same technology to download data from compatible FDA cleared blood glucose meters. Both the subject and predicate device are able to analyze blood glucose meter data producing basic statistics and graphs.

Summary:

Based on the information provided in this premarket notification, the Glooko device system for Glooko Logbook+ Application is substantially equivalent to the predicate device and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Glooko, Inc.
C/O Shilpa Mydur
170A University Avenue
PALO ALTO CA 94301

April 25, 2013

Re: K130886
Trade/Device Name: Glooko Device System for Glooko Logbook+ Application
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: March 27, 2013
Received: March 29, 2013

Dear Shilpa Mydur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Denise Johnson-lyles -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number if Known: N/A

Device Name: Glooko Device System for Glooko Logbook+ Application

Indications for Use:

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The Glooko device system for Glooko Logbook+ Application is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

Prescription Use ____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130886